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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,878	08/01/2003	Cohava Gelber	PDC 126	3037

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EXAMINER	
NIEBAUER, RONALD T	
ART UNIT	PAPER NUMBER
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,878	GELBER ET AL.	
	Examiner	Art Unit	
	Ronald T. Niebauer	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-36 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-36 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to the examiner's contact information listed at the end of this action.

The rejections and/or objections made in the prior action mailed 8/24/06 which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants reply and amendment filed 1/5/07 is acknowledged and will be addressed to the extent that they pertain to the present grounds of rejection.

Claims 1, 3-36, 38 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(Maintained) Claim 28 and dependent claims (29-33) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The

rejection is maintained for the reasons set forth in the previous Office Actions and herein below. Applicants argue that the phrase 'contacting steps' is clear. Claim 28 and dependent claims are indefinite because claim 28 does not clearly refer to the contacting step of claim 1 and claim 1 is open to comprising multiple contacting steps. Claims 29-33 are rejecting for depending from indefinite claims. Alternative language such as 'wherein the contacting step is repeated' would clarify the subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

(Maintained/new for claim 38) Claims 1, 3-6, 8-18, 20-24, 26, 28, 33-36, 38 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6107497 (previously cited). The rejection is maintained for the reasons set forth in the previous Office Actions and herein below. Applicants argue that the reference does not disclose administration into a cell and does not disclose the enhancement of transport. Amendments have been made to specifically recite transport into a cell and contacting in vivo. Applicants have made similar arguments previously; hence examiner is reiterating the argument and addressing the effect of the amendments and the newly added claim (claim 38). Note that new claim 38 includes limitations deleted from claim 1, so the limitations of claim 38 and dependent claims have been addressed in previous actions. It is noted that the claims do not require any particular degree of enhancement and therefore require only that the transport be increased to some small degree relative to the absence of diketopiperazine.

US 6107497 teach a method of drug delivery comprising a complex of diketopiperazine and drug to be delivered. In one embodiment the delivery occurs via microparticles. With regard to the argument that the method 'enhances transport', the same compound is taught and used as instantly claimed then inherently the compounds would share the same bio-effecting characteristics. The rejection is based on the fact that the method steps are the same including the compound as instantly claimed. In Section 2112 of the MPEP it is stated:

> 'The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103.... the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.'

One of ordinary skill in the art would see that the two compounds of US 6107497 and of the instant claims, respectively, would inherently have the same characteristics.

An example is provided (example 1 of US 6107497) to show that the administration can be performed directly and in vivo. Further, (column 10 line 14) it is stated that 'the microparticles can be delivered to specific cells'. Regarding claim 38, there is no mention of immunological issues outside of one specific arrangement of components intended for administration as an antigen (column 9 line 12). Therefore it is inferred that there are not particular concerns with immunological responses.

Taken together, the claim limitations (claims 1, 3-6, 8-18, 20-24, 26, 28, 33-36, 38) are anticipated by US 6107497 and therefore the rejection is maintained.

(Maintained) Claims 1, 4-10, 13-36 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6652885 B2 (previously cited). The rejection is maintained for the reasons set forth in the previous Office Actions and herein below. Applicants argue that the reference does not disclose or suggest enhancing transport across a cell membrane and delivering of a compound directly into a cell. Applicants have made similar arguments previously; hence examiner is reiterating the argument and addressing the effect of the amendments.

As stated above, the rejection is based on the fact that the method steps are the same including the compound as instantly claimed. US 6652885 B2 teach a complex of a component such as a protein and diketopiperazine (abstract). The patent also teaches 'formulations and methods also are provided for the improved transport of

active agents across biological membranes' (abstract and column 3 line 42). Further, it is stated that 'the diketopiperazines also serve both to stabilize and **enhance delivery** of the entrapped materials. Formulations also have been developed for the **enhanced transport** of active agents across biological membranes' (column 4 line 12). One of ordinary skill in the art would see that the two compounds of US 6652885 B2 and of the instant claims, respectively, would have the same characteristics since it is stated that diketopiperazines enhance delivery. It is also stated that, 'the compositions can be administered to any targeted biological membrane' (column 10 line 54). Since a cell membrane/lipid bilayer fall within the scope of any biological membrane, the patent clearly discloses enhanced transport across a cell membrane/lipid bilayer and delivery into a cell. Taken together the claim limitations (claims 1, 4-10, 13-36) are anticipated by US 6652885 B2 and therefore the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(Maintained) Claims 1, 3-36, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6107497 in combination with US 6652885 B2. The rejection is maintained for the reasons set forth in the previous Office Actions and herein below. Applicants argue that neither patent discloses or suggests a method for enhancing

transport of a compound across a cell membrane. As stated above, US 6652885 B2 teach 'the diketopiperazines also serve both to stabilize and **enhance delivery** of the entrapped materials. Formulations also have been developed for the **enhanced transport** of active agents across biological membranes' (column 4 line 12). Hence, all elements of the claimed methods are disclosed.

Both references teach compounds comprising an active agent encapsulated by diketopiperazine microparticles for administration. One would be motivated to combine the references because US 6071497 itself is referenced in US 6652885 (column 2 line 58) and mentioned as work to improve upon (column 2-3). It would have been obvious to one skilled in the art at the time of the invention to determine all operable and optimum component ratio, doses, etc. because the component ratios, doses are an art-recognized variable that is routinely determined and optimized in the art. One would have an expectation for success based on the examples provided

Hence, the rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald T. Niebauer whose telephone number is 571-270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DANIEL M. SULLIVAN, PH.D.
PRIMARY EXAMINER